UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

DEFENDANT RICHARD F. SELDEN'S NOTICE OF FILING JOINT STATUS REPORT REGARDING FDA COMPLIANCE WITH DEFENDANT'S SUBPOENAS

In an attempt to secure discovery vital to his defense in this action, on October 28, 2005 -- the first day he was permitted to do so by the Federal Rules of Civil Procedure -- defendant Richard F. Selden ("Dr. Selden") caused two federal subpoenas to be issued out of the U.S. District Court for the District of Columbia and served upon the United States Food and Drug Administration ("FDA").

On August 16, 2006, more than nine months after Dr. Selden first sought FDA discovery and more than eight months after moving to compel the FDA's compliance with the subpoenas, U.S. District Judge Ricardo M. Urbina issued an Order in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.), granting Dr. Selden's motion to compel FDA compliance in its entirety (the "D.C. Order"). The D.C. Order and Memorandum Opinion is attached as Exhibit A hereto.

Pursuant to the D.C. Order, Dr. Selden and the FDA have filed in the U.S. District Court for the District of Columbia a Joint Status Report Regarding FDA

Compliance With Defendant Richard F. Selden's Federal Subpoenas and submit a courtesy copy to this Court, attached as Exhibit B hereto.

As the Court will see, there are still several issues to be addressed. For example, notwithstanding the pretrial schedule in this action (which, among other things, provides that all written discovery must be completed by October 30, 2006), the FDA has taken the position that it will take 22 months to comply with the subpoenas. Therefore, if Dr. Selden cannot resolve this dispute shortly, he intends to seek relief before this Court.

Dated: August 25, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Justin J. Daniels

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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 25, 2006.

Dated: August 25, 2006

/s/ Justin J. Daniels
Justin J. Daniels

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

ORDER

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

For the reasons stated in the Memorandum Opinion contemporaneously filed herewith, it is this 16th day of August, 2006,

ORDERED that defendant Selden's motion to compel is **GRANTED**, and it is

FURTHER ORDERED that the FDA's motion to quash is **DENIED**, and it is

ORDERED that the FDA comply with Selden's subpoenas in accordance with the FDA's *Touhy* regulations, and it is

FURTHER ORDERED that the parties provide this court (and a courtesy copy to the trial court in Massachusetts) with a joint status report outlining the parties' anticipated timing for

the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The parties must file their joint status report within 7 days of this order.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

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[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id.*

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Miscellaneous Case No. 05-0476 (RMU)
v.	:	(Related Case: Civ. No. 05-11805-NMG Pending in the United States District
RICHARD F. SELDEN,	:	Court for the District of Massachusetts)
Defendant,	:	
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	
Interested Party.	:	

JOINT STATUS REPORT REGARDING FDA COMPLIANCE WITH DEFENDANT RICHARD F. SELDEN'S FEDERAL SUBPOENAS

Pursuant to this Court's August 16, 2006 Order granting defendant Richard F. Selden's ("Dr. Selden's") motion to compel the United States Food and Drug Administration's ("FDA's") compliance with two federal subpoenas issued by Dr. Selden out of this Court on October 28, 2005, Dr. Selden and the FDA (collectively, the "Parties") respectfully submit this joint status report regarding the scope and expected timing for FDA compliance.

Exhibit A, attached hereto, provides the current status of FDA compliance with each of the thirteen requests for documents contained in Dr. Selden's "Schedule A" to the subpoenas, along with FDA's proposed timing for completed production.

Exhibit B, attached hereto, identifies five open issues, along with a summary of the Parties' respective positions. Dr. Selden respectfully requests a conference before the Court to address these issues.

Respectfully submitted,

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Food and Drug Administration

August 25, 2006

CERTIFICATE OF SERVICE

I, _____, hereby certify that on August 25, 2006, I caused a true copy of the foregoing Joint Status Report Regarding FDA Compliance With Defendant Richard F. Selden's Federal Subpoenas to be served by U.S. mail upon:

Frank Huntington
United States Securities and Exchange Commission
Boston District Office
33 Arch Street, 23rd Floor
Boston, Massachusetts 02110

Dated: August 25, 2006

_____

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
1. All FDA documents relating to FDA's consideration of surrogate endpoints for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, including, but not limited to, all: A) internal FDA correspondence and documents relating to Dr. Selden, TKT, Replagal, the Fabrazyme Biologic License Application ("BLA"), or any Fabrazyme-related Investigational New Drug Application ("IND"); and B) materials from the Jan. 2003 FDA advisory committee meeting relating to Replagal or Fabrazyme. FDA will not produce: - documents submitted by TKT - Fabrazyme documents relating exclusively to chemistry, manufacturing, or controls ("CMC") - Fabrazyme documents generated after 4/23/03	A) FDA has an estimated 15,375 pages of potentially responsive documents, requiring 768 hours of review time. Anticipated production date uncertain.[2] B) FDA has an estimated 3,500 pages of potentially responsive documents, requiring 175 hours of review time. Anticipated production date uncertain.
2. All FDA documents relating to FDA's consideration of dual approval for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 4, 6, and 7.	See timing for Schedule A request 1.
3. Every complete response letter ("CRL") issued by the FDA's Center For Biologics Evaluation And Review ("CBER") from 1987 to the present.	**Open Issue, see Ex. B infra.**	If this request is narrowed to include every CRL issued by CBER in 2000 and 2001, subject to the criteria listed below in Exhibit B, FDA has identified 30 CRLs responsive to this request, totaling an estimated 393 pages and requiring 20 hours of review time. Anticipated production date of 10/3/06.
4. All documents relating to Replagal.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 6, and 7.	See timing for Schedule A request 1.
5. All documents relating to TKT but not to Replagal.	No production necessary.	N/A

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
6. All documents relating to Dr. Selden.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 4, and 7.	See timing for Schedule A request 1.
7. All documents relating to Fabrazyme through 4/24/03.	FDA will produce all: A) CRLs sent to Genzyme regarding Fabrazyme; B) Genzyme responses to Fabrazyme CRLs, except portions relating exclusively to CMC; C) correspondence between Genzyme and FDA, in addition to CRLs and CRL responses, relating to Fabrazyme; D) portions of the original Fabrazyme BLA or any Fabrazyme-related IND relating to clinical, safety, efficacy and/or clinical trials; E) internal FDA correspondence and documents relating to the Fabrazyme BLA or any Fabrazyme-related IND, except documents generated after 4/23/03; and F) materials from the Jan. 2003 FDA advisory committee meeting relating to Fabrazyme, except the meeting transcript and materials submitted by TKT.	A) FDA has already identified an estimated 25 pages of responsive documents, requiring 1.25 hours of review time. Anticipated production date of 9/29/06. B) FDA has an estimated 75 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 7,500 to 37,500 pages) of potentially responsive documents, requiring between 375 and 1,875 hours of review time. Anticipated production date uncertain. C) Anticipated production date of 12/31/06. D) FDA has an estimated 46 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 4,600 to 23,000 pages) of potentially responsive documents, requiring between 230 and 1,150 hours of review time. This estimate does not include any documents from any Fabrazyme-related INDs, which may contain even more potentially responsive documents. Anticipated production date uncertain. E) See timing for Schedule A request 1. F) See timing for Schedule A request 1.
8. All documents relating to the SEC lawsuit or any other actual/possible lawsuit involving TKT or Replagal.	FDA will produce all responsive documents, except: - documents submitted by TKT - documents unrelated to Replagal	FDA has an estimated 500 pages of potentially responsive documents. Anticipated production date of 12/31/06.

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
9. All guidelines for CBER review of BLAs, INDs, trials, protocols, etc.	FDA will produce any internal FDA manuals, guidelines or templates available for reference or use, as of January 1, 1996 or later, in connection with the review of a BLA or IND.	FDA has an estimated 41,000 pages of responsive documents, requiring 2050 hours of review time. Anticipated production date uncertain.
10. Record retention schedules under 21 C.F.R. § 20.23(c)	FDA will produce its Headquarters Record Control Schedule, last updated on 12/31/89, which FDA represents was the applicable record retention schedule for the period 1990 to present.	FDA has already collected 104 pages of responsive documents. Anticipated production date of 9/1/06.
11. All documents relating to the dissolution/potential dissolution of CBER.	No production necessary.	N/A
12. Any proposed or final documents relating to guiding public disclosure of BLA status.	FDA will produce any internal FDA proposals or draft guidelines relating to the public disclosure, by the applicant, of the status of the applicant's BLA.	FDA's preliminary search has not identified any documents responsive to this request.
13. All documents relating to joint FDA/SEC coordination.	FDA will produce all correspondence and communications, and all documents reflecting, memorializing or referring to any correspondence or communications, between FDA and the SEC relating to Dr. Selden, TKT, Replagal, or any joint FDA/SEC efforts to enhance inter-agency cooperation.	In addition to those documents identified as responsive to Schedule A Request 8, FDA has an estimated additional 1000 pages of potentially responsive documents. Anticipated production date of 12/31/06.

[1] Productions will be made by four different components within FDA on a rolling basis, and the anticipated production date is the final date by which the production of this category of documents will be completed by all FDA components. Estimates of the number of FDA staff hours necessary for production are based on an estimated 3 minutes per page for review and redaction of documents. FDA will provide a privilege log no later than 90 days after the completion of the production of each category of documents described above.

[2] See Exhibit B, Open Issue 1.

Exhibit B

Issue #1: Timing of FDA production of documents

FDA's position:

FDA is unable to provide the Court with an exact date for its completion of production of all documents responsive to Subpoena Requests 1, 2, 4, 6, 7(B), (D)-(F), and 13 because FDA's initial search has identified an estimated 120,375 pages of documents that are potentially responsive to these requests. Presently, FDA estimates that it will take two months to collect and organize these documents and twenty months to complete the review, redaction, and supervisory review of the redactions (assuming three full-time employees are assigned to work on this project for six to eight hours per day, and spend approximately 3 minutes per page for review and redaction). Thus, based on an estimated volume of up to 120,375 pages of documents, the total time to production is expected to be twenty-two months from the day the search begins. FDA will make every effort to adhere to this timeframe. If less than 120,375 pages of documents are ultimately identified, or if Dr. Selden is able to further refine his request as outlined below, the review and redaction times can be reduced proportionately (e.g., if only 71,975 pages are identified, the time to production could be reduced to about thirteen months). If more than 120,375 pages are ultimately identified, the review and redaction times would be increased (e.g., if 140,000 pages are identified, the time to production would increase to twenty-seven months).

With respect to Subpoena Request 7(B), FDA has immediately available the three CRLs that FDA sent to Genzyme relating to its Fabrazyme product, as well as the table of contents for Genzyme's responses to these three CRLs. With respect to Subpoena Request 7(D), FDA has immediately available the table of contents for the portions of the original BLA for Fabrazyme that relate to clinical safety and efficacy, as well as a Genzyme-prepared overview of the clinical safety and efficacy portion of the original BLA for Fabrazyme. In the interest of prioritizing the

Exhibit B

FDA resources that must be marshaled to produce documents pursuant to this request, FDA proposes to provide Dr. Selden with these tables of contents and overviews so that Dr. Selden can identify the order of priority for production of the documents that are responsive to this request. If Dr. Selden is willing to narrow his request using these materials, the time required by FDA for the production of the documents he seeks could be significantly reduced.

Dr. Selden's Position:

The Court in the District of Massachusetts has already extended the pre-trial calendar in SEC v. Selden by six months to accommodate FDA's delay in responding to the subpoenas. The current schedule now requires all written discovery to be completed by October 30, 2006, with all depositions to be completed by end of February 2007. Nevertheless, the FDA now says that it will need another 22 months -- or until the middle of 2008 -- to complete the production. Surely this could not be the "prompt" FDA response that the Court had in mind when granting Dr. Selden's motion to compel (see Memorandum Opinion, Docket Entry No. 19 at 7 n.7), given that it would render the subpoenas essentially meaningless. Further, it would deny Dr. Selden a fair defense against a government enforcement action brought with the assistance of FDA itself. Lastly, FDA's proposed 22-month schedule is not defensible because it does not jibe with the realities of litigation document review. For example, under FDA's estimate, it will take six weeks for one person to review and process a single box of documents.[3] Even a conservative estimate of the review time for a box of documents in a complex litigation would be no more than 4-5 days per box, a period that can be accelerated with additional resource commitment or,

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[3] This figure is derived as follows: The FDA estimates a total production of 120,375 pages of documents. One standard size file box (or "banker's box") can hold approximately 2,500-3,000 pages of documents. FDA says it will take three people 22 months to complete this production, meaning that one person will need 22 months to complete approximately 13-16 boxes, or 6-7 weeks per box, per person.

Exhibit B

specific to FDA, a waiver of the deliberative process privilege (see Issue #3, below). Thus, the Court should order FDA to comply with the subpoenas on an accelerated basis by October 30, 2006, the end of the written discovery period in SEC v. Selden.

Issue #2: Request No. 3[4]

(A) Time range for CRLs to be produced

FDA's position:

FDA has agreed to produce every CRL issued by CBER between January 1, 2000 and December 31, 2001, excluding those CRLs issued for products that were never approved, those CRLs sent in response to Biologic License Application ("BLA") supplements rather than original applications, and those CRLs issued for products for which user fees were not collected. Applying these criteria to narrow Dr. Selden's request ensures that only CRLs issued for products with applications that are similar to Replagal's application will be produced. The January 1, 2000 and December 31, 2001 time period proposed by FDA will result in the production of all such CRLs for the year proceeding and the year following FDA's issuance of the Replagal CRL, which was issued in January 2001.

FDA has identified 30 CRLs for products fitting the above criteria that were issued during the relevant two-year time period. This search required twelve hours of FDA staff time, the review and redaction of these CRLs will require an additional 20 hours, and production

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[4] Request No. 3 of Schedule A calls for "[e]very complete response letter ('CRL') issued by the FDA's Center For Biologics Evaluation And Review ('CBER') from 1987 to the present." The SEC v. Selden case concerns the Complete Response Letter of Transkaryotic Therapies, Inc. ("TKT"). In that action, the SEC alleges Dr. Selden fraudulently misrepresented what the CRL said and meant. Complete Response Letters (sometimes referred to as "Complete Review Letters" or "CRLs") are "issued [by CBER] when the complete review indicates that there are deficiencies remaining that preclude the approval of the application or supplement at that time. The Complete Response Letter will: Summarize all of the deficiencies remaining, and [w]here appropriate, describe actions necessary to place the application/supplement in a condition for approval." CBER Manual Of Standard Operating Procedures And Policies ("SOPP") 8405, version #4 (eff. Sept. 20, 2004). The definition of CRL has also been revised several times during the relevant period.

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should be complete by 10/3/06. If FDA were ordered to produce every CRL issued by CBER during the 18-year period sought by Dr. Selden, the resulting massive undertaking would require years of FDA staff time to search for, organize, review, redact, and produce the estimated 400,000 pages of responsive documents. As FDA has consistently maintained, such a request is "unduly burdensome and over broad" because it seeks documents "more than 18 years old," encompasses "many thousands of pages," and would thus "further strain FDA's already overburdened document production capacity." FDA Motion to Quash at 4, 8.

Dr. Selden's Position:

FDA's refusal to produce CRLs beyond the years 2000 and 2001 is a new position that FDA took only in the last three weeks. Nevertheless, Dr. Selden is willing to agree to a protocol that would make the production non-burdensome on FDA (see 2.B., below), but FDA has not been willing to discuss this option.

(B) Open issue regarding production of CRLs for unapproved products

FDA's position:

FDA may not produce any CRLs for products that have not been approved because its regulations forbid FDA from releasing any information regarding unapproved BLA's. See 21 C.F.R. § 601.51(b) ("The existence of a biological product file will not be disclosed by the Food and Drug Administration before a biologics license application has been approved unless it has previously been disclosed or acknowledged."). The very existence of a BLA for a product that has not yet received FDA approval may be considered trade secret and confidential commercial information ("CCI"), and FDA's release of such information could constitute a violation of both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and the Federal Trade Secrets Act, 18 U.S.C. § 1905, both of which carry individual criminal liability. See Jerome Stevens Pharms.

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v. FDA, 319 F. Supp. 2d 45 (D.D.C. 2004), aff'd in part, rev'd in part, 420 F.3d 1249 (D.C. Cir. 2005) (seeking $1.345 billion in damages for FDA's alleged release of trade secret and CCI contained in a new drug application).

Neither of these statutes, nor FDA's regulations, provide for an "attorneys' eyes only" exception for the release of trade secret or CCI. Should the court order FDA to produce the CRLs that Dr. Selden seeks, FDA would need to alert the hundreds of entities to whom these unapproved CRLs were issued during this 18-year period to permit them to intervene in the present action to defend their proprietary information. See 21 C.F.R. § 20.48 (requiring FDA to give notice to "a person who will be affected by a proposed disclosure of data or information contained in Food and Drug records" to permit them "to institute suit in a United States District Court to enjoin release of the records" and prohibiting FDA from "disclos[ing] the records involved until the matter and all related appeals have been concluded").

Dr. Selden's Position:

FDA's stated position derives from a premise not at issue here; namely, that Dr. Selden is seeking the public disclosure of confidential information. Not so. Dr. Selden's interest in the materials is limited to defending himself in the government enforcement action; and FDA regulations specifically provide a process for limited disclosure of non-public information in connection with court proceedings:

> Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

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21 C.F.R. § 20.86 ("Disclosure in administrative or court proceedings") (emphasis added). Further, contrary to FDA's blanket assertion that it cannot produce any non-public information without an extensive notice period and the exhaustion of all legal remedies by those affected, FDA regulations contemplate production subject to measures that can be adopted "to reduce disclosure to the minimum necessary under the circumstances."

Consistent with the above, Dr. Selden is willing to agree to the entry of a protective order that would protect the confidentiality of the CRLs while permitting him limited use for purposes of his defense. However, to date FDA has refused to engage in any dialogue on what measures FDA believes are appropriate. Dr. Selden has already offered the following: first, Dr. Selden will agree to an order precluding the use of any non-public information outside of the SEC v. Selden litigation; second, Dr. Selden will agree to a protocol that limits CRL access to "attorneys' eyes only"; and third, Dr. Selden will agree that if information from the CRLs is referred to (by an expert, for example), such reference will not include the applicant name or product; but rather refer to a numerical identifier (e.g., "CRL #1").

Issue #3: FDA Assertion Of "Deliberative Process" Privilege Over Entire Production

FDA's position:

FDA is not intending to assert the deliberative process privilege over every document responsive to the subpoena. Indeed, Selden correctly asserts that FDA waived its deliberative process privilege with respect to a limited number of documents provided to the SEC in a completely unrelated matter, but the circumstances of that decision differed markedly from those in the present action. For instance, FDA disclosed the documents at issue in that case to the SEC pursuant to FDA regulations that permit the inter-agency sharing of documents. See 21 U.S.C. § 20.85.

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With respect to any assertion of the deliberative process privilege, FDA does not believe that this issue is ripe for decision at this point in the litigation. FDA will not agree to summarily waive the deliberative process privilege before the agency has had a chance to assert the privilege in regards to specific documents and provide the Court with the reasoning for the assertion on a privilege log. FDA believes, however, and has consistently maintained, that Dr. Selden's requests seek "disclosure of information that is or contains . . . pre-decisional, and/or agency deliberative process information that is protected from disclosure under the applicable laws, regulations, or privileges." See FDA November 9, 2005 Letter (Attached to Selden's Motion to Compel Memo as Attachment D). A consistent policy of withholding information subject to the deliberative process privilege encourages full and frank discussion among FDA decisionmakers. See 21 C.F.R. § 20.62 (permitting intra-agency writings to be withheld from public disclosure); see also Dep't of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions,' by protecting open and frank discussion among those who make them within the Government.").

Moreover, FDA's decision to withhold privileged information in the present litigation must be analyzed anew, within the confines of the present action. See In re Sealed Case, 121 F.3d 729, 737-738 (D.C. Cir. 1997) ("Each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests, taking into account factors such as the relevance of the evidence, the availability of other evidence, the seriousness of the litigation, the role of the government, and the possibility of future timidity by government employees.") (internal citation and quotation marks omitted). The Court's failure to perform a

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"fresh" review of FDA's assertion of the deliberative process privilege would not only negatively impact frank discussions among agency employees, but would also be a strong disincentive for the agency to ever agree to a waiver of the privilege, regardless of the circumstances. Because FDA has not to date asserted the deliberative process privilege in a concrete setting, the issue is not ripe for judicial consideration.

Dr. Selden's Position:

Until very recently, FDA stated that it was contemplating a waiver of the "deliberative process" privilege in this action as it did in the virtually identical SEC v. Biopure action. However, it now says it will not waive the privilege, but that it is premature to discuss its decision in court. FDA's denial of Dr. Selden's request is manifestly ripe for the Court's decision. For several reasons, FDA's decision is both arbitrary and unreasonable.

First, as recently as June 28, 2006, the FDA agreed to waive the privilege, in its entirety, in a virtually identical pending litigation in the District of Massachusetts also brought by the SEC and involving the same regulatory branch of FDA. See SEC v. Biopure Corp., et al., Civ. No. 05-11853-PBS (D. Mass., filed Sept. 15, 2005). There is no sound basis for denying Dr. Selden the same. For example, FDA's only stated reason for asserting the privilege in this case in contrast to Biopure is that the Biopure request came under 21 C.F.R. § 20.85, which provides for the inter-agency sharing of information. See FDA's Position, above. However, both FDA and the SEC have already agreed to use § 20.85 in this case, the same procedure used in Biopure, to request this information from FDA, thus rendering FDA's sole distinction non-existent.

Second, the FDA's only stated justification for asserting the privilege -- that it would "negatively impact frank discussions among agency employees" -- is inapplicable in this case

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because Dr. Selden is not seeking to disclose FDA information to the public, and is willing to agree to a protective order that expressly precludes it.

Third, the effect of the FDA's position would be to eviscerate perhaps the most important reason the subpoenas were issued in the first place; namely, to obtain an understanding of the FDA's own reactions and interpretations of its discussions with the company, Dr. Selden, and the product application.

Issue #4: Depositions of FDA employees

FDA's position:

The subpoenas served upon FDA by Dr. Selden in the present action also requested the depositional testimony of the FDA and the CBER records custodians. Dr. Selden has informed FDA that he seeks such testimony in order to authenticate the records produced by FDA pursuant to these subpoenas. In lieu of these depositions, FDA proposes to authenticate its records via Rule 902 of the Federal Rules of Evidence, consistent with FDA's standard practice when providing documents for use in third-party litigation. see 21 C.F.R. § 20.3 (providing for the certification and authentication of FDA records).

Dr. Selden now seeks to impermissibly expand the present action to encompass his demands for the testimony of four FDA scientists. Such testimony was requested by Dr. Selden pursuant to FDA's Touhy regulations in a letter dated March 29, 2006, See 21 C.F.R. § 20.1, well after the instant litigation was begun. Thus, this request is not part of the current case. After carefully considering this request, FDA permitted Dr. Selden to obtain the testimony of Dr. Walton, the FDA scientist who was previously deposed by the SEC. See FDA Letter dated June 30, 2006. FDA refused to grant Dr. Selden's request for the testimony of the three remaining

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scientists, citing, among other concerns, "FDA's limited resources and the vast number of requests the agency receives for its personnel to testify."

As this Court has already acknowledged, these "subpoenas for testimony are not at issue here." Memorandum Opinion, Aug. 16, 2006, p.3 n.2. FDA's response to Dr. Selden's request for testimony pursuant to FDA's Touhy regulations may only be challenged by Dr. Selden under an arbitrary and capricious standard of review in an action under the Administrative Procedure Act ("APA"). Far from being a "meaningless gesture" as Dr. Selden contends below, such a requirement is well established by the longstanding precedent of this Circuit. See Houston Bus. Journal, Inc. v. Office of the Comptroller, 86 F.3d 1208, 1212 n.4 (D.C. Cir. 1996) (directing third-party litigant to "proceed under the APA, and the federal court will review the agency's decision not to permit its employee to testify under an 'arbitrary and capricious' standard").

Dr. Selden's Position:

Referenced by the Court in its Aug. 16, 2006 Memorandum Opinion (see p. 3 n.2), the testimony of FDA employees Karen Weiss, Duane Rieves and James Kaiser -- which Dr. Selden requested pursuant to FDA's "Touhy" regulations -- are central to his defense and he objects to FDA's refusal to make them available.

The only stated basis for FDA's denial of the testimony is that it would be "duplicative" of Dr. Walton. (FDA's reference above to "other concerns" having been identified in the letter is misleading. The letter specifically stated that it was denying Dr. Selden's request on the basis of the supposed "duplicative" nature of the testimony.) FDA's position is demonstrably false, as Dr. Selden has already communicated to FDA.

Further, with respect to any burden on FDA, Dr. Selden is willing to conduct the depositions during off hours and at any location. A similar procedure was approved by the Court

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for FDA depositions in In re: Vioxx Products Liability Litig., No. MDL 1657, 2006 WL 784878, *12 (E.D. La. Mar. 15, 2006).

Finally, FDA's suggestion of Dr. Selden bringing a separate APA action for relief is, with all due respect, a meaningless gesture under these particular circumstances; where there is an ongoing enforcement action brought by the SEC with the assistance of FDA (including the FDA's permission of "off the record" interviews by SEC of several FDA employees), and is now heading for trial.

Issue #5: Payment of costs for production of FDA documents

FDA's position:

FDA intends to renew its request that Selden be responsible for the significant costs associated with responding to his voluminous subpoena requests, which FDA estimates will require it to dedicate thousands of staff hours in order to produce over 120,000 pages of responsive documents. See Fed. R. Civ. P. 45(c)(2)(B) ("[A]n order to compel production shall protect any person who is not a party . . . from significant expense resulting from the inspection and copying command."). In Northrop Corp. v. McDonnell Douglas Corp, the D.C. Circuit instructed courts to "fully recognize the burden of imposing on a non-party the effort and expense of discovery, particularly when the expense will be borne by the taxpayers." 751 F.2d 395, 407 (D.C. Cir. 1984); see also Linder v. Calero-Portocarrero, 251 F.3d 178, 182 (D.C. Cir. 2001) (concluding that "fee shifting was mandatory" under Rule 45 and requiring the requestor to bear all of the government's nearly $200,000 in costs).

If Dr. Selden's production was being conducted in response to a FOIA request rather than pursuant to a subpoena, the search and review charges would be $40.00 per hour for mid-grade employees, and duplication costs would be $0.10 per page based on the current fee schedule.

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See 21 C.F.R. § 20.45. Based on an estimated volume of up to 120,375 pages of documents and the assignment of three full-time, mid-grade employees for 6 hours per day for twenty-two months, the duplication costs would be approximately $12,000 and the search and review charges would be approximately $317,000.

Dr. Selden's Position:

Dr. Selden, a private citizen, is being accused of fraud by the federal government in an enforcement action that almost certainly would not have been brought without the assistance of FDA. The FDA's involvement in this case stems back to the earliest phases of the SEC's investigation. Having supplied critical assistance to the SEC, including "off the record" interviews of key witnesses, the FDA now wants Dr. Selden to bear the burden and expense of seeking discovery from the very agency that is behind the lawsuit against him. This is unfair and inappropriate.